K014286

MAR 8 2002

510(k) Summary

2/19/02

Onux Medical, Inc. Contact Person:	Ruthann DePietro
Trade or Proprietary Name:	Salute
Common or Usual Name:	Endoscopic stapler and staple
Classification Name:	Endoscopic and/or Accessory, Implantable Staple
Classification Number	GDW

Devices to Which Equivalence is Claimed

The ProTack™ laparoscopic stapler currently sold by Auto Suture (United States Surgical) and a variety of Ethicon staples (e.g. Proximate™ staples).

Description of Subject Device

A minor modification has been made to the Salute staples in that a coating has been added to the surface of the staples.

A reusable surgical instrument with integral disposable cartridge for placing coated stainless steel constructs. This instrument may be used laparoscopically with 5mm trocars.

Intended Use of Subject Device

The modification will not change the intended use of the device in any way from its original intended use.

The Salute Fixation System is indicated for use in a variety of laparoscopic / endoscopic or open surgical procedures for fixation of prosthetic material and approximation of tissue.

Comparison of Technical Aspects

The subject device modification is also incorporated in the ProTack™ laparoscopic staples and the Ethicon staples. The subject device and these equivalent devices use the same type of coating for the same purpose.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

Ms. Ruthann DePietro
Vice President, Quality Assurance
and Regulatory Affairs
Onux Medical, Inc.
5 Merrill Drive
Hampton, New Hampshire 03842

Re: K014286
Trade/Device Name: Salute
Regulation Number: 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: December 21, 2001
Received: December 27, 2001

Dear Ms. DePietro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014286

Device Name: Salute

Indications For Use:

The Salute Fixation System is indicated for use in a variety of laparoscopic / endoscopic or open surgical procedures for fixation of prosthetic material and approximation of tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014286